

*West Virginia Department of Environmental Protection  
Division of Air Quality*

*Joe Manchin III  
Governor*

*Stephanie R. Timmermeyer  
Cabinet Secretary*

# Permit to Operate



*Pursuant to  
**Title V**  
of the Clean Air Act*

*Issued to:*  
Mylan Pharmaceuticals  
Morgantown  
R30-06100033-2006

---

*John A. Benedict  
Director*

*Issued: December 12, 2006 • Effective: January 1, 2007*  
*Expiration: December 12, 2011 • Renewal Application Due: June 12, 2011*

Permit Number: **R30-06100033-2006**  
Permittee: **Mylan Pharmaceuticals Inc.**  
Facility Name: **Chestnut Ridge Plant**  
Mailing Address: 781 Chestnut Ridge Road, Morgantown, WV 26505

---

*This permit is issued in accordance with the West Virginia Air Pollution Control Act (West Virginia Code §§ 22-5-1 et seq.) and 45CSR30 — Requirements for Operating Permits. The permittee identified at the above-referenced facility is authorized to operate the stationary sources of air pollutants identified herein in accordance with all terms and conditions of this permit.*

---

Facility Location:	Morgantown, Monongalia County, West Virginia
Mailing Address:	PO Box 4310, Morgantown, WV 26504-4310
Telephone Number:	(304) 599-2595
Type of Business Entity:	Publicly Owned and Operated
Facility Description:	Pharmaceutical Compounding and Formulating
SIC Codes:	2834
UTM Coordinates:	589.6 km Easting • 4390.1 km Northing • Zone 17

*Any person whose interest may be affected, including, but not necessarily limited to, the applicant and any person who participated in the public comment process, by a permit issued, modified or denied by the Secretary may appeal such action of the Secretary to the Air Quality Board pursuant to article one [§§ 22B-1-1 et seq.], Chapter 22B of the Code of West Virginia. West Virginia Code §22-5-14.*

---

*Issuance of this Title V Operating Permit does not supersede or invalidate any existing permits under 45CSR13, 14 or 19, although all applicable requirements from such permits governing the facility's operation and compliance have been incorporated into the Title V Operating Permit.*

## Table of Contents

<b>1.0.</b>	<b>Emission Units and Active R13, R14, and R19 Permits .....</b>	<b>4</b>
1.1.	Emission Units .....	4
1.2.	Active R13, R14, and R19 Permits .....	10
<b>2.0.</b>	<b>General Conditions.....</b>	<b>11</b>
2.1.	Definitions .....	11
2.2.	Acronyms .....	11
2.3.	Permit Expiration and Renewal .....	12
2.4.	Permit Actions .....	12
2.5.	Reopening for Cause .....	12
2.6.	Administrative Permit Amendments .....	13
2.7.	Minor Permit Modifications .....	13
2.8.	Significant Permit Modification.....	13
2.9.	Emissions Trading .....	13
2.10.	Off-Permit Changes .....	13
2.11.	Operational Flexibility .....	14
2.12.	Reasonably Anticipated Operating Scenarios .....	15
2.13.	Duty to Comply.....	15
2.14.	Inspection and Entry .....	15
2.15.	Schedule of Compliance .....	16
2.16.	Need to Halt or Reduce Activity not a Defense .....	16
2.17.	Emergency .....	16
2.18.	Federally-Enforceable Requirements.....	17
2.19.	Duty to Provide Information .....	17
2.20.	Duty to Supplement and Correct Information .....	17
2.21.	Permit Shield .....	17
2.22.	Credible Evidence.....	18
2.23.	Severability .....	18
2.24.	Property Rights .....	18
2.25.	Acid Deposition Control.....	18
<b>3.0.</b>	<b>Facility-Wide Requirements .....</b>	<b>20</b>
3.1.	Limitations and Standards.....	20
3.2.	Monitoring Requirements .....	21
3.3.	Testing Requirements .....	21
3.4.	Recordkeeping Requirements .....	22
3.5.	Reporting Requirements .....	24
3.6.	Compliance Plan .....	26
3.7.	Permit Shield .....	26
<b>4.0.</b>	<b>Source-Specific Requirements - Boilers.....</b>	<b>28</b>
4.1.	Limitations and Standards.....	28
4.2.	Monitoring Requirements .....	29
4.3.	Testing Requirements .....	29
4.4.	Recordkeeping Requirements .....	30
4.5.	Reporting Requirements .....	30
4.6.	Compliance Plan .....	30

<b>5.0.</b>	<b>Source-Specific Requirements – Fluid Bed Granulators .....</b>	<b>31</b>
5.1.	Limitations and Standards.....	31
5.2.	Monitoring Requirements .....	31
5.3.	Testing Requirements .....	32
5.4.	Recordkeeping Requirements .....	32
5.5.	Reporting Requirements .....	<del>32</del> <a href="#">33</a>
5.6.	Compliance Plan .....	<del>32</del> <a href="#">33</a>
<b>6.0.</b>	<b>Source-Specific Requirements - Rotoclones .....</b>	<b><del>33</del><a href="#">34</a></b>
6.1.	Limitations and Standards.....	<del>33</del> <a href="#">34</a>
6.2.	Monitoring Requirements .....	<del>34</del> <a href="#">35</a>
6.3.	Testing Requirements .....	<del>34</del> <a href="#">35</a>
6.4.	Recordkeeping Requirements .....	<del>34</del> <a href="#">35</a>
6.5.	Reporting Requirements .....	<del>34</del> <a href="#">35</a>
6.6.	Compliance Plan .....	<del>34</del> <a href="#">35</a>
<b>7.0.</b>	<b>Source-Specific Requirements – Coating Pans .....</b>	<b><del>35</del><a href="#">36</a></b>
7.1.	Limitations and Standards.....	<del>35</del> <a href="#">36</a>
7.2.	Monitoring Requirements .....	<del>35</del> <a href="#">37</a>
7.3.	Testing Requirements .....	<del>35</del> <a href="#">38</a>
7.4.	Recordkeeping Requirements .....	<del>36</del> <a href="#">38</a>
7.5.	Reporting Requirements .....	<del>36</del> <a href="#">38</a>
7.6.	Compliance Plan .....	<del>36</del> <a href="#">38</a>
<b>8.0.</b>	<b>Source-Specific Requirements – Regenerative Thermal Oxidizer (RTO) and Catalytic Oxidizer (CO).....</b>	<b>39</b>
8.1.	Limitations and Standards.....	39
8.2.	Monitoring Requirements .....	40
8.3.	Testing Requirements .....	41
8.4.	Recordkeeping Requirements .....	41
8.5.	Reporting Requirements .....	41
8.6.	Compliance Plan .....	41

## 1.0 Emission Units and Active R13, R14, and R19 Permits

### 1.1 Emission Units

Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID</a> & Emission Unit Description	Design Capacity	Year Installed/Modified
001	None	001	<a href="#">Boiler 3</a> : Natural gas boiler	6.27 MMBtu/hr	1987
002	None	002	<a href="#">Boiler 4</a> : Natural gas boiler	1.5 MMBtu/hr	1987
003	None	003	<a href="#">Boiler 5</a> : Natural gas boiler	6.00 MMBtu/hr	1991
004	None	004	<a href="#">Boiler 2</a> : Natural gas boiler	1.18 MMBtu/hr	1974
006	None	006	<a href="#">Boiler 1</a> : Natural gas boiler	3.34 MMBtu/hr	1968
007	None	007	<a href="#">Boiler 7</a> : Natural gas boiler	6.99 MMBtu/hr	1997
008	None	008	<a href="#">Boiler 8</a> : Natural gas boiler	6.99 MMBtu/hr	1997
009	None	009	<a href="#">Boiler 11</a> : Natural gas boiler	2.07 MMBtu/hr	2000
009	None	009A	<a href="#">Boiler 12</a> : Natural gas boiler	2.07 MMBtu/hr	2000
010	None	010	<a href="#">Boiler 15</a> : Natural gas boiler	7 MMBtu/hr	2004
011	None	011	<a href="#">Boiler 2343</a> : Natural gas boiler	21.0 MMBtu/hr	2005
012	None	012	<a href="#">Boiler 2344</a> : Natural gas boiler	21.0 MMBtu/hr	2005
013	None	013	<a href="#">Boiler 2345</a> : Natural gas boiler	21.0 MMBtu/hr	2005
014	None	014	<a href="#">Boiler 2674</a> : Natural gas boiler	0.65 MMBtu/hr	2005
015	None	015	<a href="#">Boiler 2675</a> : Natural gas boiler	0.65 MMBtu/hr	2005
210	210	210	<a href="#">Coating Pan 169</a> : Coating pan controlled by cartridge collector <a href="#">EF169</a>	500 lb/load	1985
215	215*	215	<a href="#">Coating Pan 1390</a> : Coating pan controlled by cartridge collector <a href="#">EF1390</a>	<a href="#">500 750</a> lb/load	1999
220	220	220	<a href="#">Coating Pan 186</a> : Coating pan controlled by cartridge collector <a href="#">EF186</a>	500 lb/load	1986
230	230	230	<a href="#">Coating Pan 217</a> : Coating pan controlled by cartridge collector <a href="#">EF217</a>	500 lb/load	1987
240	240	240	<a href="#">Coating Pan 99</a> : Coating pan controlled by cartridge collector <a href="#">EF99</a>	500 lb/load	1983
<a href="#">241</a>	<a href="#">241</a> *	<a href="#">241</a>	<a href="#">Coating Pan 4549</a> : Coating Pan controlled by cartridge collector <a href="#">4553</a>	<a href="#">750</a> lb/load	<a href="#">2009</a>
<a href="#">242</a>	<a href="#">242</a> *	<a href="#">242</a>	<a href="#">Coating Pan 4027</a> : Coating Pan controlled by cartridge collector <a href="#">4101</a>	<a href="#">245</a> lb/load	<a href="#">2008</a>
<a href="#">243</a>	<a href="#">243</a>	<a href="#">243</a>	<a href="#">Coating Pan 3853</a> : Coating Pan controlled by cartridge collector <a href="#">4164</a>	<a href="#">750</a> lbs/load	<a href="#">2008</a>
<a href="#">244</a>	<a href="#">244</a> *	<a href="#">244</a>	<a href="#">Coating Pan TBD</a> : Coating Pan controlled by cartridge collector <a href="#">TBD</a>	<a href="#">750</a> lb/load	<a href="#">2010</a>

Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID</a> & Emission Unit Description	Design Capacity	Year Installed/Modified
280	280	Rooms 74-101 – 74-122, 74-129	<a href="#">Rotoclone 4:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1992 (Rotoclone)
281	281	Rooms 74-151, 74-153, 91-129, 91-130, 91-132, 91-134 – 91-137, 91-139, 91-229, 91-230, 91-232, 91-329, 91-330, 91-332, 91-334 – 91-337	<a href="#">Rotoclone 3:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1991 (Rotoclone)
282	282	Rooms 74-150, 74-152, 74-154, 74-159, 74-160, 74-161, 74-162, 74-212, 91-232, 91-233	<a href="#">Rotoclone 1:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1982 (Rotoclone)
283	283	Rooms 74-205 – 74-209, 99-217 – 99-219	<a href="#">Rotoclone 2:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1982 (Rotoclone)
287	287*	Rooms <a href="#">BL203</a> , <a href="#">BL206</a> , <a href="#">BL207</a> , BL209, BL211, BL214, BL304, <a href="#">BL306</a> , <a href="#">BL307</a> , BL309- BL314, BL316, BL402 – BL404, BL406- BL414, BL416, <a href="#">BL422</a>	<a href="#">Rotoclone 6:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1996 (Rotoclone)
288	288*	Rooms BB101- BB106, <a href="#">BB106</a> , BB108-BB111, BB113-BB118, <a href="#">BB122</a> , BB201- BB203, BB206- BB208, BB210- BB217, <a href="#">BB303</a> , BB312	<a href="#">Rotoclone 5:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1996 (Rotoclone)
291	291*	Rooms 85-205A – 85-208A, 99-105, 99-114 – 99-122, 99-209, <a href="#">99-211</a> , ORG201A – ORG203A, <a href="#">ORG204A</a> , <a href="#">ORG204B</a>	<a href="#">Rotoclone 7:</a> Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	1999 (Rotoclone)

Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID</a> & Emission Unit Description	Design Capacity	Year Installed/Modified
294	294*	<del>Rooms 85-102, 85-104, 85-107, 85-110, BB112, 85-106, 85-108, 85-114, 85-115</del> <a href="#">Rooms BB112, 85-106, 85-108, 85-114, 85-115, 85-102, 85-104, 85-107, 85-110</a>	<a href="#">Rotoclone 9</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2003 (Rotoclone)
295	295*	Rooms BL218, BL219, <del>BL421</del>	<a href="#">Rotoclone 10</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2004 (Rotoclone)
296	296*	Rooms NEX140, NEX142, NEX144, NEX146, NEX159 - NEX162	<a href="#">Rotoclone 2317</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
297	297*	Rooms NEX139, NEX141, NEX143, NEX145, NEX152 - NEX158, NEX163, NEX164	<a href="#">Rotoclone 2318</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
298	298*	Rooms NEX131 - NEX136, NEX138, NEX147, NEX148	<a href="#">Rotoclone 2319</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
299	299*	Rooms <del>NEX130A</del> , NEX175, NEX177, NEX179, NEX181, NEX183	<a href="#">Rotoclone 2320</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
300	300*	Rooms NEX176, NEX178, NEX180, NEX182, NEX186 - NEX189	<a href="#">Rotoclone 2321</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)



Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID &amp; Emission Unit Description</a>	Design Capacity	Year Installed/Modified
305	305*	Rooms <a href="#">NEX211A–NEX217A</a> , <a href="#">NEX231</a> , <a href="#">NEX232</a> , <a href="#">NEX234</a> , <a href="#">NEX275–NEX283</a> , <a href="#">NEX286–NEX289</a>	<a href="#">Rotoclone 2322</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
306	306*	Rooms <a href="#">NEX240–NEX255</a> , <a href="#">NEX211A–217A</a>	<a href="#">Rotoclone 2323</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
307	307*	Rooms NEX372, NEX374, NEX376, NEX378, NEX380	<a href="#">Rotoclone 2324</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
308	308*	Rooms NEX349, NEX362, NEX364, NEX366, NEX368, NEX369	<a href="#">Rotoclone 2325</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
309	309*	Rooms NEX346, NEX355, NEX357, NEX359 - NEX361	<a href="#">Rotoclone 2326</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
310	310*	Rooms NEX375, NEX377, NEX379, NEX381	<a href="#">Rotoclone 2327</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
311	311*	Rooms <a href="#">NEX305–NEX312</a> , <a href="#">NEX316</a> , <a href="#">NEX 216A</a> , <a href="#">NEX217A</a> , <a href="#">NEX535–NEX538</a>	<a href="#">Rotoclone 2328</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
312	312*	Rooms NEX321 - NEX330, NEX421 – NEX430	<a href="#">Rotoclone 2329</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
313	313*	Rooms NEX303, <a href="#">NEX403</a> , NEX405 - NEX412	<a href="#">Rotoclone 2330</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)

Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID</a> & Emission Unit Description	Design Capacity	Year Installed/Modified
314	314*	Rooms NEX468, NEX469, NEX472 - NEX480	<a href="#">Rotoclone 2331</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
315	315*	Rooms NEX435 - NEX438, NEX413 - NEX416, NEX419, <a href="#">NEX445J</a>	<a href="#">Rotoclone 2332</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
316	316*	Rooms NEX464 - NEX467, NEX481, NEX482, NEX484 - NEX494 <a href="#">2</a>	<a href="#">Rotoclone 2333</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
317	317*	Rooms <a href="#">NEX445B</a> , <a href="#">NEX445C</a> , <a href="#">NEX445D</a> , <a href="#">NEX305</a> , <a href="#">NEX312</a> , <a href="#">NEX316</a>	<a href="#">Rotoclone 2334</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
318	318*	Rooms NEX445B, <a href="#">NEX445C</a> , <a href="#">NEX445D</a> , <a href="#">NEX445E</a> , NEX445F, NEX445G	<a href="#">Rotoclone 2335</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
319	319*	Rooms NEX514, NEX516 <a href="#">A-D</a> , NEX522 -NEX524, NEX526, NEX528, NEX530, NEX535 - NEX538	<a href="#">Rotoclone 2336</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)

Emission Point ID	Control Device	Emission Unit ID	<a href="#">Mylan ID</a> & Emission Unit Description	Design Capacity	Year Installed/Modified
320	320*	Rooms NEX503, NEX505, NEX507, NEX509, NEX511, NEX513, <del>NEX515</del>	<a href="#">Rotoclone 2337</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
321	321*	Rooms NEX506, NEX508, NEX510, NEX512, <a href="#">NEX515</a>	<a href="#">Rotoclone 2338</a> : Pharmaceutical manufacturing equipment serviced by Rotoclone	Varies	2005 (Rotoclone)
533	533*	533	<a href="#">Fluid Bed 527</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF527</a>	Up to 550 Kg/Load	1991
534	534*	534	<a href="#">Fluid Bed 473</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF473</a>	Up to <del>15400</del> Kg/Load	1997
535	535*	535	<a href="#">Fluid Bed 1339</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF1339</a>	Up to 550 Kg/Load	1997
536	536*	536	<a href="#">Fluid Bed 1222</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF1222</a>	Up to <del>15400</del> Kg/Load	1997
537	537*	537	<a href="#">Fluid Bed 1552</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF1552</a>	Up to 550 Kg/Load	1997
538	538*	538	<a href="#">Fluid Bed 1855</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF1855</a>	Up to <del>15400</del> Kg/Load	2002
571	571*	571	<a href="#">Fluid Bed 2113</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF2113</a>	Up to 550 Kg/Load	2004
572	572*	572	<a href="#">Fluid Bed 2181</a> : Fluid bed granulator controlled by cartridge collector <a href="#">EF2181</a>	Up to <del>15400</del> Kg/Load	2004
573	573*	573	<a href="#">Fluid Bed 2811</a> : Fluid bed granulator controlled by cartridge collector <a href="#">3340</a>	Up to 550 Kg/Load	2006
574	574*	574	<a href="#">Fluid Bed 3287</a> : Fluid bed granulator controlled by cartridge collector <a href="#">3416</a>	Up to <del>10054</del> Kg/Load	2006
575	575*	575	<a href="#">Fluid Bed 3620</a> : Fluid bed granulator controlled by cartridge collector <a href="#">3643</a>	Up to <del>550 154</del> Kg/Load	<del>TBD</del> <a href="#">2007</a>
576	576*	576	<a href="#">Fluid Bed 3426</a> : Fluid bed granulator controlled by cartridge collector <a href="#">3407</a>	Up to 550 Kg/Load	<del>TBD</del> <a href="#">2007</a>

Emission Point ID	Control Device	Emission Unit ID	<u>Mylan ID &amp; Emission Unit Description</u>	Design Capacity	Year Installed/Modified
577	577*	577	<u>Fluid Bed 3704</u> : Fluid bed granulator controlled by cartridge collector <u>3881</u>	Up to <del>400-154</del> Kg/Load	<del>TBD</del> <u>2008</u>
578	578*	578	<u>Fluid Bed 3705</u> : Fluid bed granulator controlled by cartridge collector <u>3879</u>	Up to 550 Kg/Load	<del>TBD</del> <u>2008</u>
579	579*	579	<u>Fluid Bed 4001</u> : Fluid bed granulator controlled by cartridge collector <u>4287</u>	Up to 550 Kg/Load	<del>TBD</del> <u>2008</u>
580	580*	580	Fluid bed granulator controlled by cartridge collector	Up to 550 Kg/Load	TBD
581	581*	581	Fluid bed granulator controlled by cartridge collector	Up to 550 Kg/Load	TBD
582	582*	582	Fluid bed granulator controlled by cartridge collector	Up to 550 Kg/Load	TBD
N/A	None	N/A	Class I or Class II CFC-containing Equipment Subject to 40 CFR Part 82 Subpart F	Varies	Varies
<u>TBD</u>	<u>None</u>	<u>TBD</u>	<u>Catalytic Oxidizer</u>	<u>1.25 mmBtu/hr</u> <u>450 lbs/hr</u>	<u>2010</u>
<u>TBD</u>	<u>None</u>	<u>TBD</u>	<u>Regenerative Thermal Oxidation<sup>(1)</sup></u>	<u>13.75 mmBtu/hr</u> <u>3,070 lbs/hr</u>	<u>2010</u>

\*Identifies pollution control equipment included in R13-2068H K.

<sup>(1)</sup>Permittee authorized to operate one or two RTO units with aggregate design capacity as given.

## 1.2. Active R13, R14, and R19 Permits

The underlying authority for any conditions from R13, R14, and/or R19 permits contained in this operating permit is cited using the original permit number (e.g. R13-1234). The current applicable version of such permit(s) is listed below.

Permit Number	Date of Issuance
R13-2068 <u>JK</u>	<u>June 13, 2007</u> <u>January 5, 2010</u>

## 2.0 General Conditions

### 2.1. Definitions

- 2.1.1. All references to the "West Virginia Air Pollution Control Act" or the "Air Pollution Control Act" mean those provisions contained in W.Va. Code §§ 22-5-1 to 22-5-18.
- 2.1.2. The "Clean Air Act" means those provisions contained in 42 U.S.C. §§ 7401 to 7671q, and regulations promulgated thereunder.
- 2.1.3. "Secretary" means the Secretary of the Department of Environmental Protection or such other person to whom the Secretary has delegated authority or duties pursuant to W.Va. Code §§ 22-1-6 or 22-1-8 (45CSR§30-2.12.). The Director of the Division of Air Quality is the Secretary's designated representative for the purposes of this permit.

### 2.2. Acronyms

<b>CAAA</b>	Clean Air Act Amendments	<b>NSPS</b>	New Source
<b>CBI</b>	Confidential Business Information		Performance Standards
<b>CEM</b>	Continuous Emission Monitor	<b>PM</b>	Particulate Matter
<b>CES</b>	Certified Emission Statement	<b>PM<sub>10</sub></b>	Particulate Matter less than 10µm in diameter
<b>C.F.R. or CFR</b>	Code of Federal Regulations		
<b>CO</b>	Carbon Monoxide	<b>pph</b>	Pounds per Hour
<b>C.S.R. or CSR</b>	Codes of State Rules	<b>ppm</b>	Parts per Million
<b>DAQ</b>	Division of Air Quality	<b>PSD</b>	Prevention of Significant Deterioration
<b>DEP</b>	Department of Environmental Protection	<b>psi</b>	Pounds per Square Inch
<b>FOIA</b>	Freedom of Information Act	<b>SIC</b>	Standard Industrial Classification
<b>HAP</b>	Hazardous Air Pollutant		
<b>HON</b>	Hazardous Organic NESHAP	<b>SIP</b>	State Implementation Plan
<b>HP</b>	Horsepower		
<b>lbs/hr or lb/hr</b>	Pounds per Hour	<b>SO<sub>2</sub></b>	Sulfur Dioxide
<b>LDAR</b>	Leak Detection and Repair	<b>TAP</b>	Toxic Air Pollutant
<b>M</b>	Thousand	<b>TPY</b>	Tons per Year
<b>MACT</b>	Maximum Achievable Control Technology	<b>TRS</b>	Total Reduced Sulfur
		<b>TSP</b>	Total Suspended Particulate
<b>MM</b>	Million		
<b>MMBtu/hr or mmbtu/hr</b>	Million British Thermal Units per Hour	<b>USEPA</b>	United States Environmental Protection Agency
<b>MMCF/hr or mmcf/hr</b>	Million Cubic Feet Burned per Hour	<b>UTM</b>	Universal Transverse Mercator
<b>NA</b>	Not Applicable		
<b>NAAQS</b>	National Ambient Air Quality Standards	<b>VEE</b>	Visual Emissions Evaluation
<b>NESHAPS</b>	National Emissions Standards for Hazardous Air Pollutants	<b>VOC</b>	Volatile Organic Compounds
<b>NO<sub>x</sub></b>	Nitrogen Oxides		

### **2.3. Permit Expiration and Renewal**

- 2.3.1. Permit duration. This permit is issued for a fixed term of five (5) years and shall expire on the date specified on the cover of this permit, except as provided in 45CSR§30-6.3.b. and 45CSR§30-6.3.c.  
**[45CSR§30-5.1.b.]**
- 2.3.2. A permit renewal application is timely if it is submitted at least six (6) months prior to the date of permit expiration.  
**[45CSR§30-4.1.a.3.]**
- 2.3.3. Permit expiration terminates the source's right to operate unless a timely and complete renewal application has been submitted consistent with 45CSR§30-6.2. and 45CSR§30-4.1.a.3.  
**[45CSR§30-6.3.b.]**
- 2.3.4. If the Secretary fails to take final action to deny or approve a timely and complete permit application before the end of the term of the previous permit, the permit shall not expire until the renewal permit has been issued or denied, and any permit shield granted for the permit shall continue in effect during that time.  
**[45CSR§30-6.3.c.]**

### **2.4. Permit Actions**

- 2.4.1. This permit may be modified, revoked, reopened and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.  
**[45CSR§30-5.1.f.3.]**

### **2.5. Reopening for Cause**

- 2.5.1. This permit shall be reopened and revised under any of the following circumstances:
- a. Additional applicable requirements under the Clean Air Act or the Secretary's legislative rules become applicable to a major source with a remaining permit term of three (3) or more years. Such a reopening shall be completed not later than eighteen (18) months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions has been extended pursuant to 45CSR§30-6.6.a.1.A. or B.
  - b. Additional requirements (including excess emissions requirements) become applicable to an affected source under Title IV of the Clean Air Act (Acid Deposition Control) or other legislative rules of the Secretary. Upon approval by U.S. EPA, excess emissions offset plans shall be incorporated into the permit.
  - c. The Secretary or U.S. EPA determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.
  - d. The Secretary or U.S. EPA determines that the permit must be revised or revoked and reissued to assure compliance with the applicable requirements.

**[45CSR§30-6.6.a.]**

## **2.6. Administrative Permit Amendments**

- 2.6.1. The permittee may request an administrative permit amendment as defined in and according to the procedures specified in 45CSR§30-6.4.  
**[45CSR§30-6.4.]**

## **2.7. Minor Permit Modifications**

- 2.7.1. The permittee may request a minor permit modification as defined in and according to the procedures specified in 45CSR§30-6.5.a.  
**[45CSR§30-6.5.a.]**

## **2.8. Significant Permit Modification**

- 2.8.1. The permittee may request a significant permit modification, in accordance with 45CSR§30-6.5.b., for permit modifications that do not qualify for minor permit modifications or as administrative amendments.  
**[45CSR§30-6.5.b.]**

## **2.9. Emissions Trading**

- 2.9.1. No permit revision shall be required, under any approved economic incentives, marketable permits, emissions trading, and other similar programs or processes for changes that are provided for in the permit and that are in accordance with all applicable requirements.  
**[45CSR§30-5.1.h.]**

## **2.10. Off-Permit Changes**

- 2.10.1. Except as provided below, a facility may make any change in its operations or emissions that is not addressed nor prohibited in its permit and which is not considered to be construction nor modification under any rule promulgated by the Secretary without obtaining an amendment or modification of its permit. Such changes shall be subject to the following requirements and restrictions:
- a. The change must meet all applicable requirements and may not violate any existing permit term or condition.
  - b. The permittee must provide a written notice of the change to the Secretary and to U.S. EPA within two (2) business days following the date of the change. Such written notice shall describe each such change, including the date, any change in emissions, pollutants emitted, and any applicable requirement that would apply as a result of the change.
  - c. The change shall not qualify for the permit shield.
  - d. The permittee shall keep records describing all changes made at the source that result in emissions of regulated air pollutants, but not otherwise regulated under the permit, and the emissions resulting from those changes.
  - e. No permittee may make any change subject to any requirement under Title IV of the Clean Air Act (Acid Deposition Control) pursuant to the provisions of 45CSR§30-5.9.

- f. No permittee may make any changes, which would require preconstruction review under any provision of Title I of the Clean Air Act (including 45CSR14 and 45CSR19) pursuant to the provisions of 45CSR§30-5.9.

**[45CSR§30-5.9.]**

**2.11. Operational Flexibility**

- 2.11.1. The permittee may make changes within the facility as provided by § 502(b)(10) of the Clean Air Act. Such operational flexibility shall be provided in the permit in conformance with the permit application and applicable requirements. No such changes shall be a modification under any rule or any provision of Title I of the Clean Air Act (including 45CSR14 and 45CSR19) promulgated by the Secretary in accordance with Title I of the Clean Air Act and the change shall not result in a level of emissions exceeding the emissions allowable under the permit.

**[45CSR§30-5.8]**

- 2.11.2. Before making a change under 45CSR§30-5.8., the permittee shall provide advance written notice to the Secretary and to U.S. EPA, describing the change to be made, the date on which the change will occur, any changes in emissions, and any permit terms and conditions that are affected. The permittee shall thereafter maintain a copy of the notice with the permit, and the Secretary shall place a copy with the permit in the public file. The written notice shall be provided to the Secretary and U.S. EPA at least seven (7) days prior to the date that the change is to be made, except that this period may be shortened or eliminated as necessary for a change that must be implemented more quickly to address unanticipated conditions posing a significant health, safety, or environmental hazard. If less than seven (7) days notice is provided because of a need to respond more quickly to such unanticipated conditions, the permittee shall provide notice to the Secretary and U.S. EPA as soon as possible after learning of the need to make the change.

**[45CSR§30-5.8.a.]**

- 2.11.3. The permit shield shall not apply to changes made under 45CSR§30-5.8., except those provided for in 45CSR§30-5.8.d. However, the protection of the permit shield will continue to apply to operations and emissions that are not affected by the change, provided that the permittee complies with the terms and conditions of the permit applicable to such operations and emissions. The permit shield may be reinstated for emissions and operations affected by the change:

- a. If subsequent changes cause the facility's operations and emissions to revert to those authorized in the permit and the permittee resumes compliance with the terms and conditions of the permit, or
- b. If the permittee obtains final approval of a significant modification to the permit to incorporate the change in the permit.

**[45CSR§30-5.8.c.]**

- 2.11.4. "Section 502(b)(10) changes" are changes that contravene an express permit term. Such changes do not include changes that would violate applicable requirements or contravene enforceable permit terms and conditions that are monitoring (including test methods), recordkeeping, reporting, or compliance certification requirements.

**[45CSR§30-2.39]**



## **2.12. Reasonably Anticipated Operating Scenarios**

2.12.1. The following are terms and conditions for reasonably anticipated operating scenarios identified in this permit.

- a. Contemporaneously with making a change from one operating scenario to another, the permittee shall record in a log at the permitted facility a record of the scenario under which it is operating and to document the change in reports submitted pursuant to the terms of this permit and 45CSR30.
- b. The permit shield shall extend to all terms and conditions under each such operating scenario; and
- c. The terms and conditions of each such alternative scenario shall meet all applicable requirements and the requirements of 45CSR30.

**[45CSR§30-5.1.i.]**

## **2.13. Duty to Comply**

2.13.1. The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the West Virginia Code and the Clean Air Act and is grounds for enforcement action by the Secretary or USEPA; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

**[45CSR§30-5.1.f.1.]**

## **2.14. Inspection and Entry**

2.14.1. The permittee shall allow any authorized representative of the Secretary, upon the presentation of credentials and other documents as may be required by law, to perform the following:

- a. At all reasonable times (including all times in which the facility is in operation) enter upon the permittee's premises where a source is located or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- c. Inspect at reasonable times (including all times in which the facility is in operation) any facilities, equipment (including monitoring and air pollution Control equipment), practices, or operations regulated or required under the permit;
- d. Sample or monitor at reasonable times substances or parameters to determine compliance with the permit or applicable requirements or ascertain the amounts and types of air pollutants discharged.

**[45CSR§30-5.3.b.]**

## **2.15. Schedule of Compliance**

- 2.15.1. For sources subject to a compliance schedule, certified progress reports shall be submitted consistent with the applicable schedule of compliance set forth in this permit and 45CSR§30-4.3.h., but at least every six (6) months, and no greater than once a month, and shall include the following:
- a. Dates for achieving the activities, milestones, or compliance required in the schedule of compliance, and dates when such activities, milestones or compliance were achieved; and
  - b. An explanation of why any dates in the schedule of compliance were not or will not be met, and any preventative or corrective measure adopted.

**[45CSR§30-5.3.d.]**

## **2.16. Need to Halt or Reduce Activity not a Defense**

- 2.16.1. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. However, nothing in this paragraph shall be construed as precluding consideration of a need to halt or reduce activity as a mitigating factor in determining penalties for noncompliance if the health, safety, or environmental impacts of halting or reducing operations would be more serious than the impacts of continued operations.

**[45CSR§30-5.1.f.2.]**

## **2.17. Emergency**

- 2.17.1. An "emergency" means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error.

**[45CSR§30-5.7.a.]**

- 2.17.2. Effect of any emergency. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emission limitations if the conditions of 45CSR§30-5.7.c. are met.

**[45CSR§30-5.7.b.]**

- 2.17.3. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:

- a. An emergency occurred and that the permittee can identify the cause(s) of the emergency;
- b. The permitted facility was at the time being properly operated;
- c. During the period of the emergency the permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and

- d. Subject to the requirements of 45CSR§30-5.1.c.3.C.1, the permittee submitted notice of the emergency to the Secretary within one (1) working day of the time when emission limitations were exceeded due to the emergency and made a request for variance, and as applicable rules provide. This notice, report, and variance request fulfills the requirement of 45CSR§30-5.1.c.3.B. This notice must contain a detailed description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

**[45CSR§30-5.7.c.]**

- 2.17.4. In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof.

**[45CSR§30-5.7.d.]**

- 2.17.5. This provision is in addition to any emergency or upset provision contained in any applicable requirement.

**[45CSR§30-5.7.e.]**

## **2.18. Federally-Enforceable Requirements**

- 2.18.1. All terms and conditions in this permit, including any provisions designed to limit a source's potential to emit and excepting those provisions that are specifically designated in the permit as "State-enforceable only", are enforceable by the Secretary, USEPA, and citizens under the Clean Air Act.

**[45CSR§30-5.2.a.]**

- 2.18.2. Those provisions specifically designated in the permit as "State-enforceable only" shall become "Federally-enforceable" requirements upon SIP approval by the USEPA.

## **2.19. Duty to Provide Information**

- 2.19.1. The permittee shall furnish to the Secretary within a reasonable time any information the Secretary may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Secretary copies of records required to be kept by the permittee. For information claimed to be confidential, the permittee shall furnish such records to the Secretary along with a claim of confidentiality in accordance with 45CSR31. If confidential information is to be sent to USEPA, the permittee shall directly provide such information to USEPA along with a claim of confidentiality in accordance with 40 C.F.R. Part 2.

**[45CSR§30-5.1.f.5.]**

## **2.20. Duty to Supplement and Correct Information**

- 2.20.1. Upon becoming aware of a failure to submit any relevant facts or a submittal of incorrect information in any permit application, the permittee shall promptly submit to the Secretary such supplemental facts or corrected information.

**[45CSR§30-4.2.]**

## **2.21. Permit Shield**

- 2.21.1. Compliance with the conditions of this permit shall be deemed compliance with any applicable requirements as of the date of permit issuance provided that such applicable requirements are included and are specifically

identified in this permit or the Secretary has determined that other requirements specifically identified are not applicable to the source and this permit includes such a determination or a concise summary thereof.

**[45CSR§30-5.6.a.]**

2.21.2. Nothing in this permit shall alter or affect the following:

- a. The liability of an owner or operator of a source for any violation of applicable requirements prior to or at the time of permit issuance; or
- b. The applicable requirements of the Code of West Virginia and Title IV of the Clean Air Act (Acid Deposition Control), consistent with § 408 (a) of the Clean Air Act.
- c. The authority of the Administrator of U.S. EPA to require information under § 114 of the Clean Air Act or to issue emergency orders under § 303 of the Clean Air Act.

**[45CSR§30-5.6.c.]**

## **2.22. Credible Evidence**

2.22.1. Nothing in this permit shall alter or affect the ability of any person to establish compliance with, or a violation of, any applicable requirement through the use of credible evidence to the extent authorized by law. Nothing in this permit shall be construed to waive any defenses otherwise available to the permittee including but not limited to any challenge to the credible evidence rule in the context of any future proceeding.

**[45CSR§30-5.3.e.3.B. and 45CSR38]**

## **2.23. Severability**

2.23.1. The provisions of this permit are severable. If any provision of this permit, or the application of any provision of this permit to any circumstance is held invalid by a court of competent jurisdiction, the remaining permit terms and conditions or their application to other circumstances shall remain in full force and effect.

**[45CSR§30-5.1.e.]**

## **2.24. Property Rights**

2.24.1. This permit does not convey any property rights of any sort or any exclusive privilege.

**[45CSR§30-5.1.f.4]**

## **2.25. Acid Deposition Control**

2.25.1. Emissions shall not exceed any allowances that the source lawfully holds under Title IV of the Clean Air Act (Acid Deposition Control) or rules of the Secretary promulgated thereunder.

- a. No permit revision shall be required for increases in emissions that are authorized by allowances acquired pursuant to the acid deposition control program, provided that such increases do not require a permit revision under any other applicable requirement.
- b. No limit shall be placed on the number of allowances held by the source. The source may not, however, use allowances as a defense to noncompliance with any other applicable requirement.

- c. Any such allowance shall be accounted for according to the procedures established in rules promulgated under Title IV of the Clean Air Act.

**[45CSR§30-5.1.d.]**

- 2.25.2. Where applicable requirements of the Clean Air Act are more stringent than any applicable requirement of regulations promulgated under Title IV of the Clean Air Act (Acid Deposition Control), both provisions shall be incorporated into the permit and shall be enforceable by the Secretary and U. S. EPA.

**[45CSR§30-5.1.a.2.]**

### 3.0 Facility-Wide Requirements

#### 3.1. Limitations and Standards

- 3.1.1. **Open burning.** The open burning of refuse by any person, firm, corporation, association or public agency is prohibited except as noted in 45CSR§6-3.1.  
[45CSR§6-3.1.]
- 3.1.2. **Open burning exemptions.** The exemptions listed in 45CSR§6-3.1 are subject to the following stipulation: Upon notification by the Secretary, no person shall cause, suffer, allow or permit any form of open burning during existing or predicted periods of atmospheric stagnation. Notification shall be made by such means as the Secretary may deem necessary and feasible.  
[45CSR§6-3.2.]
- 3.1.3. **Asbestos.** The permittee is responsible for thoroughly inspecting the facility, or part of the facility, prior to commencement of demolition or renovation for the presence of asbestos and complying with 40 C.F.R. § 61.145, 40 C.F.R. § 61.148, and 40 C.F.R. § 61.150. The permittee must notify the Secretary at least ten (10) working days prior to the commencement of any asbestos removal on the forms prescribed by the Secretary if the permittee is subject to the notification requirements of 40 C.F.R. § 61.145(b)(3)(i). A copy of this notice is required to be sent to the USEPA, the Division of Waste Management and the Bureau for Public Health - Environmental Health.  
[40 C.F.R. 61 and 45CSR15]
- 3.1.4. **Odor.** No person shall cause, suffer, allow or permit the discharge of air pollutants, which cause or contribute to an objectionable odor at any location occupied by the public.  
[45CSR§4-3.1 State-Enforceable only.]
- 3.1.5. **Standby plan for reducing emissions.** When requested by the Secretary, the permittee shall prepare standby plans for reducing the emissions of air pollutants in accordance with the objectives set forth in Tables I, II, and III of 45CSR11.  
[45CSR§11-5.2]
- 3.1.6. **Emission inventory.** The permittee is responsible for submitting, on an annual basis, an emission inventory in accordance with the submittal requirements of the Division of Air Quality.  
[W.Va. Code § 22-5-4(a)(14)]
- 3.1.7. **Ozone-depleting substances.** For those facilities performing maintenance, service, repair or disposal of appliances, the permittee shall comply with the standards for recycling and emissions reduction pursuant to 40 C.F.R. Part 82, Subpart F, except as provided for Motor Vehicle Air Conditioners (MVACs) in Subpart B:
- a. Persons opening appliances for maintenance, service, repair, or disposal must comply with the prohibitions and required practices pursuant to 40 C.F.R. §§ 82.154 and 82.156.
  - b. Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to 40 C.F.R. § 82.158.

- c. Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to 40 C.F.R. § 82.161.

**[40 C.F.R. 82, Subpart F]**

- 3.1.8. **Risk Management Plan.** Should this stationary source, as defined in 40 C.F.R. § 68.3, become subject to Part 68, then the owner or operator shall submit a risk management plan (RMP) by the date specified in 40 C.F.R. § 68.10 and shall certify compliance with the requirements of Part 68 as part of the annual compliance certification as required by 40 C.F.R. Part 70 or 71.

**[40 C.F.R. 68]**

- 3.1.9. The owner or operator of a plant shall maintain particulate matter control of the plant premises, and plant owned, leased or controlled access roads, by paving, application of asphalt, chemical dust suppressants or other suitable dust control measures. Good operating practices shall be implemented and when necessary particulate matter suppressants shall be applied in relation to stockpiling and general material handling to minimize particulate matter generation and atmospheric entrainment.

**[45CSR7-5.2.]**

- 3.1.10 Due to unavoidable malfunction of equipment, emissions exceeding limits set forth in 45CSR7 may be permitted by the Director for periods not to exceed ten (10) days upon specific application to the Director. Such application shall be made within twenty-four (24) hours of the malfunction. In cases of major equipment failure, additional time periods may be granted by the Director provided a corrective program has been submitted by the owner or operator and approved by the Director.

**[45CSR§7-9.1.]**

- 3.1.11. Facility-wide emissions to the atmosphere of Hazardous Air Pollutants (HAPs) shall not exceed or equal 9.4 tons per year of any single HAP or 24.4 tons per year of any combination of HAPs. Yearly total HAPs will be determined using a 12-month rolling total..

**[45CSR13, Permit No. R13-2068 (Condition 3.1.7.)]**

- 3.1.12. **Operation and Maintenance of Air Pollution Control Equipment.** The permittee shall, to the extent practicable, install, maintain, and operate all pollution control equipment, identified with an asterisk, in Section 1.1. and associated monitoring equipment in a manner consistent with safety and good air pollution control practices for minimizing emissions, or comply with any more stringent limits set forth in this permit or as set forth by any State rule, Federal regulation, or alternative control plan approved by the Secretary.

**[45CSR§13-5.11. and Permit No. R13-2068 (Condition 4.1.1.)]**

### **3.2. Monitoring Requirements**

- 3.2.1. The facility shall monitor on a monthly and yearly basis facility-wide HAP usage. Yearly HAP calculations shall be based on a 12-month rolling total.

**[45CSR13, Permit No. R13-2068 (Condition 3.2.1.)]**

### **3.3. Testing Requirements**

- 3.3.1. **Stack testing.** As per provisions set forth in this permit or as otherwise required by the Secretary, in accordance with the West Virginia Code, underlying regulations, permits and orders, the permittee shall conduct test(s) to determine compliance with the emission limitations set forth in this permit and/or established or set

forth in underlying documents. The Secretary, or his duly authorized representative, may at his option witness or conduct such test(s). Should the Secretary exercise his option to conduct such test(s), the operator shall provide all necessary sampling connections and sampling ports to be located in such manner as the Secretary may require, power for test equipment and the required safety equipment, such as scaffolding, railings and ladders, to comply with generally accepted good safety practices. Such tests shall be conducted in accordance with the methods and procedures set forth in this permit or as otherwise approved or specified by the Secretary in accordance with the following:

- a. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with 40 C.F.R. Parts 60, 61, and 63, if applicable, in accordance with the Secretary's delegated authority and any established equivalency determination methods which are applicable.
- b. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with applicable requirements which do not involve federal delegation. In specifying or approving such alternative testing to the test methods, the Secretary, to the extent possible, shall utilize the same equivalency criteria as would be used in approving such changes under Section 3.3.1.a. of this permit.
- c. All periodic tests to determine mass emission limits from or air pollutant concentrations in discharge stacks and such other tests as specified in this permit shall be conducted in accordance with an approved test protocol. Unless previously approved, such protocols shall be submitted to the Secretary in writing at least thirty (30) days prior to any testing and shall contain the information set forth by the Secretary. In addition, the permittee shall notify the Secretary at least fifteen (15) days prior to any testing so the Secretary may have the opportunity to observe such tests. This notification shall include the actual date and time during which the test will be conducted and, if appropriate, verification that the tests will fully conform to a referenced protocol previously approved by the Secretary.

[WV Code § 22-5-4(a)(15) and 45CSR13]

### 3.4. Recordkeeping Requirements

- 3.4.1. **Monitoring information.** The permittee shall keep records of monitoring information that include the following:
  - a. The date, place as defined in this permit and time of sampling or measurements;
  - b. The date(s) analyses were performed;
  - c. The company or entity that performed the analyses;
  - d. The analytical techniques or methods used;
  - e. The results of the analyses; and
  - f. The operating conditions existing at the time of sampling or measurement.

[45CSR§30-5.1.c.2.A.]



- 3.4.2. **Retention of records.** The permittee shall retain records of all required monitoring data and support information for a period of at least five (5) years from the date of monitoring sample, measurement, report, application, or record creation date. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by the permit. Where appropriate, records may be maintained in computerized form in lieu of the above records.  
**[45CSR§30-5.1.c.2.B.]**
- 3.4.3. **Odors.** For the purposes of 45CSR4, the permittee shall maintain a record of all odor complaints received, any investigation performed in response to such a complaint, and any responsive action(s) taken.  
**[45CSR§30-5.1.c. State-Enforceable only.]**
- 3.4.4. **Fugitive Dust Control Systems.** The permittee shall maintain records indicating the use of any dust suppressants or any other suitable dust control measures applied at the facility. The permittee shall also inspect all fugitive dust control systems monthly to ensure that they are operated and maintained in conformance with their designs. The permittee shall maintain records of such inspections and of all scheduled and non-scheduled maintenance of such systems. These records shall be maintained on site for five (5) years from the record creation date, stating any maintenance or corrective actions taken as a result of the monthly inspections, and the times the fugitive dust control system(s) are inoperable and any corrective actions taken.  
**[45CSR§30-5.1.c.]**
- 3.4.5. To demonstrate compliance with the facility-wide HAP limits, the permittee shall maintain monthly and yearly records of facility-wide HAP usage. The facility shall prepare monthly facility-wide calculations of the amount of each individual HAP emitted and the amount of aggregated HAPs emitted. Yearly HAP calculations shall be based on a 12-month rolling total.  
**[45CSR13, Permit No. R13-2068 (Condition 3.4.3.)]**
- 3.4.6. **Record of Maintenance of Air Pollution Control Equipment.** For all pollution control equipment identified with an asterisk in Section 1.1., the permittee shall maintain accurate records of all required pollution control equipment inspection and/or preventative maintenance procedures.  
**[45CSR13, Permit No. R13-2068 (Condition 4.2.2.)]**
- 3.4.7. **Record of Malfunctions of Air Pollution Control Equipment.** For all air pollution control equipment identified with an asterisk in Section 1.1., the permittee shall maintain records of the occurrence and duration of any malfunction or operational shutdown of the air pollution control equipment during which excess emissions occur. For each such case, the following information shall be recorded:
- The equipment involved.
  - Steps taken to minimize emissions during the event.
  - The duration of the event.
  - The estimated increase in emissions during the event.

For each such case associated with an equipment malfunction, the additional information shall also be recorded.

- e. The cause of the malfunction.
- f. Steps taken to correct the malfunction.
- g. Any changes or modifications to equipment or procedures that would help prevent future recurrences of the malfunction.

[45CSR13, Permit No. R13-2068 (Condition 4.2.3.)]

### 3.5. Reporting Requirements

- 3.5.1. **Responsible official.** Any application form, report, or compliance certification required by this permit to be submitted to the DAQ and/or USEPA shall contain a certification by the responsible official that states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate and complete.  
[45CSR§§30-4.4. and 5.1.c.3.D.]
- 3.5.2. A permittee may request confidential treatment for the submission of reporting required under 45CSR§30-5.1.c.3. pursuant to the limitations and procedures of W.Va. Code § 22-5-10 and 45CSR31.  
[45CSR§30-5.1.c.3.E.]
- 3.5.3. Except in the case of the electronic submittal requirement in 3.5.5. aAll notices, requests, demands, submissions and other communications required or permitted to be made to the Secretary of DEP and/or USEPA shall be made in writing and shall be deemed to have been duly given when delivered by hand, mailed first class or by private carrier with postage prepaid to the address(es) set forth below or to such other person or address as the Secretary of the Department of Environmental Protection may designate:

#### If to the DAQ:

Director  
WVDEP  
Division of Air Quality  
601 57<sup>th</sup> Street SE  
Charleston, WV 25304  
  
Phone: 304/926-0475  
FAX: 304/926-0478

#### If to the US EPA:

Associate Director  
Office of Enforcement and Permits Review  
(3AP12)  
U. S. Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103-2029

- 3.5.4. **Certified emissions statement.** The permittee shall submit a certified emissions statement and pay fees on an annual basis in accordance with the submittal requirements of the Division of Air Quality.  
[45CSR§30-8.]
- 3.5.5. **Compliance certification.** The permittee shall certify compliance with the conditions of this permit on the forms provided by the DAQ. In addition to the annual compliance certification, the permittee may be required

to submit certifications more frequently under an applicable requirement of this permit. The annual certification shall be submitted to the DAQ and USEPA on or before March 15 of each year, and shall certify compliance for the period ending December 31. [The annual certification submitted to USEPA shall be forwarded by e-mail only to: R3 APD Permits@epa.gov.](#) The permittee shall maintain a copy of the certification on site for five (5) years from submittal of the certification.

**[45CSR§30-5.3.e.]**

- 3.5.6. **Semi-annual monitoring reports.** The permittee shall submit reports of any required monitoring on or before September 15 for the reporting period January 1 to June 30 and on or before March 15 for the reporting period July 1 to December 31. All instances of deviation from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with 45CSR§30-4.4.

**[45CSR§30-5.1.c.3.A.]**

- 3.5.7. **Emergencies.** For reporting emergency situations, refer to Section 2.17 of this permit.

- 3.5.8. **Deviations.**

- a. In addition to monitoring reports required by this permit, the permittee shall promptly submit supplemental reports and notices in accordance with the following:

1. Any deviation resulting from an emergency or upset condition, as defined in 45CSR§30-5.7., shall be reported by telephone or telefax within one (1) working day of the date on which the permittee becomes aware of the deviation, if the permittee desires to assert the affirmative defense in accordance with 45CSR§30-5.7. A written report of such deviation, which shall include the probable cause of such deviations, and any corrective actions or preventative measures taken, shall be submitted and certified by a responsible official within ten (10) days of the deviation.
2. Any deviation that poses an imminent and substantial danger to public health, safety, or the environment shall be reported to the Director immediately by telephone or telefax. A written report of such deviation, which shall include the probable cause of such deviation, and any corrective actions or preventative measures taken, shall be submitted by the responsible official within ten (10) days of the deviation.
3. Deviations for which more frequent reporting is required under this permit shall be reported on the more frequent basis.
4. All reports of deviations shall identify the probable cause of the deviation and any corrective actions or preventative measures taken.

**[45CSR§30-5.1.c.3.C.]**

- b. The permittee shall, in the reporting of deviations from permit requirements, including those attributable to upset conditions as defined in this permit, report the probable cause of such deviations and any corrective actions or preventive measures taken in accordance with any rules of the Secretary.

**[45CSR§30-5.1.c.3.B.]**

- 3.5.9. **New applicable requirements.** If any applicable requirement is promulgated during the term of this permit, the permittee will meet such requirements on a timely basis, or in accordance with a more detailed schedule if required by the applicable requirement.

**[45CSR§30-4.3.h.1.B.]**

### 3.6. Compliance Plan

- 3.6.1. Not applicable.

### 3.7. Permit Shield

- 3.7.1. The permittee is hereby granted a permit shield in accordance with 45CSR§30-5.6. The permit shield applies provided the permittee operates in accordance with the information contained within this permit.

- 3.7.2. The following requirements specifically identified are not applicable to the source based on the determinations set forth below. The permit shield shall apply to the following requirements provided the conditions of the determinations are met.

- a. 45CSR27 – *To Prevent and Control the Emissions of Toxic Air Pollutants*. This rule does not apply to the facility because the facility currently does not have the potential to emit any such air pollutant in quantities equal to or greater than those set forth in this rule.
- b. 40 C.F.R. 60, Subpart Ka – *Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984*. This subpart does not apply to the storage tanks at the facility because the tanks do not contain a petroleum liquid and the tanks have a capacity (8,200 gallons each) less than those tanks defined as an affected facility.
- c. 40 C.F.R. 60, Subpart Kb – *Standard of Performance for Volatile Organic Liquid Storage Vessels (including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984*. This subpart does not apply to the storage tanks at the facility because the tanks were installed [in 1978] prior to July 23, 1984. Additionally, the tanks have a capacity (8,200 gallons each) less than those tanks defined as an affected facility.
- d. 40 C.F.R. 63, Subpart F – *National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry*. The facility does not manufacture any of the chemicals listed in Table I of Subpart F as a primary product..
- e. 40 C.F.R. 63, Subpart G – *National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater*. The facility is not subject to Subpart F, therefore, it is not subject to Subpart G of Part 63.
- f. 40 C.F.R. 63, Subpart FFFF – *National Standards for Miscellaneous Organic Chemical Manufacturing*. The facility does not emit hazardous air pollutants at major levels from its pharmaceutical manufacturing operations and is therefore not subject to this subpart.
- g. 40 C.F.R. 63, Subpart GGG – *National Standards for Pharmaceuticals Production*. The facility does not emit hazardous air pollutants from its pharmaceutical manufacturing operations and is therefore not subject to this subpart.
- h. 40 C.F.R. 63, Subpart DDDDD – *National Standards for Industrial, Commercial, and Institutional Boilers and Process Heaters*. The facility is a natural minor source of hazardous air pollutants and is therefore not subject to this subpart.

- i. 40 C.F.R. 64 - *Compliance Assurance Monitoring*. This facility does not have a pollutant-specific emissions unit with a control device to meet an applicable standard or limit. Therefore, the facility is not subject to the Compliance Assurance Monitoring (CAM) rule.
- j. 45CSR§2-5.1 – The facility burns natural gas only; therefore this section of 45CSR2 does not apply.
- k. 45CSR§10-4 – The facility’s manufacturing process source operations do not emit sulfur dioxide with the exception of trace amounts from natural gas combustion.
- l. 45CSR§10-5 & 45CSR§10-8 – The facility’s boilers burn only natural gas; therefore, they are exempt from the requirements of these sections of 45CSR10.
- m. 45CSR10A – *Testing, Monitoring, Recordkeeping and Reporting Requirements Under 45CSR10*. The facility’s boilers combust natural gas only; therefore, the facility is exempt from the requirements of this rule.

#### 4.0 Source-Specific Requirements • Boilers (001, 002, 003, 004, 006, 007, 008, 009, 009A, 010, 011, 012, 013, 014, 015)

##### 4.1. Limitations and Standards

- 4.1.1. No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any fuel burning unit which is greater than ten (10) percent opacity based on a six-minute block average. **[45CSR§2-3.1 and 45CSR13, Permit No. R13-2068 (Condition 5.1.1.)]**
- 4.1.2. Compliance with the visible emission requirements of 45CSR2, subsection 3.1 (4.1.1.), shall be determined in accordance with 40 C.F.R. Part 60, Appendix A, Method 9 or by using measurements from continuous opacity monitoring systems approved by the Director. The Director may require the installation, calibration, maintenance and operation of continuous opacity monitoring systems and may establish policies for the evaluation of continuous opacity monitoring results and the determination of compliance with the visible emission requirements of 4.1.1. Continuous opacity monitors shall not be required on fuel burning units, which employ wet scrubbing systems for emission control. **[45CSR§2-3.2 and 45CSR13, R13-2068 (Condition 5.1.2.)]**
- 4.1.3. The maximum amount of natural gas to be burned by a single boiler (Emission Unit ID's 007, 008, 010) shall not exceed 7,000 ft<sup>3</sup>/hr or 61,320,000 ft<sup>3</sup>/yr. **[45CSR13, Permit No. R13-2068 (Condition 5.1.9.)] (007, 008, 010)**
- 4.1.4. Maximum emissions from each boiler (007, 008, 010) shall not exceed the following limits:

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)
Carbon Monoxide	0.59	2.58
Nitrogen Oxides	0.70	3.07
Particulate (PM <sub>10</sub> )	0.10	0.30
Sulfur Dioxide	0.10	0.10
Volatile Organic Compounds	0.10	0.20

**[45CSR13, Permit No. R13-2068 (Condition 5.1.5, 5.1.6. and 5.1.7.)] (007, 008, 010)**

- 4.1.5. The three (3) Bryan Steam Corporation boilers (Emission Unit ID's 011, 012, & 013) shall combust only natural gas fuel. The maximum amount of natural gas consumed by each boiler shall not exceed ~~20,950~~ [20,590](#) ft<sup>3</sup>/hr and 180.4 million ft<sup>3</sup>/yr. **[45CSR13, Permit No. R13-2068 (Condition 5.1.10.)] (011, 012, 013)**

- 4.1.6. Each of the three (3) 21.0 MMBtu/hr Bryan Steam Corporation boilers (Emission Unit ID's 011, 012, & 013) shall not exceed the following emission rates:

<b>Pollutant</b>	<b>Maximum Hourly Emissions per Boiler (lb/hr)</b>	<b>Maximum Annual Emissions per Boiler (tpy)</b>
Carbon Monoxide	4.07	17.84
Nitrogen Oxides	2.06	9.02
Particulate (PM <sub>10</sub> )	0.20*	0.86
Sulfur Dioxide	0.02**	0.05
Volatile Organic Compounds	0.21	0.92

\*Compliance with this streamlined limit will assure compliance with 45CSR§2-4.1.b. and R13-2068 (Condition 5.1.3.).

\*\*Compliance with this streamlined limit will assure compliance with 45CSR§10-3.3.f. and R13-2068 (Condition 5.1.4.).

**[45CSR§2-4.1.b., 45CSR§10-3.3.f., and 45CSR13, Permit No. R13-2068 (Conditions 5.1.3., 5.1.4., and 5.1.8.)] (011, 012, 013)**

#### **4.2. Monitoring Requirements**

- 4.2.1. The facility shall monitor the amount of natural gas used and the hours of operation for Boilers 007, 008, 010, 011, 012, and 013 on a monthly and yearly basis. To demonstrate compliance with the emission limits and natural gas usage limits, the permittee shall record for each boiler the monthly hours of operation, and the monthly fuel consumption.

**[45CSR16, 40 C.F.R. § 60.48c(g) (Subpart Dc); 45CSR13, Permit No. R13-2068 (Conditions 5.2.2., 5.2.3., and 5.4.1.)](007, 008, 010, 011, 012, and 013)**

- 4.2.2 At such reasonable times as the Director may designate, the permittee shall conduct Method 9 emission observations for the purpose of demonstrating compliance with the opacity standards of 45CSR§2-3.1. Method 9 shall be conducted in accordance with 40 C.F.R. 60, Appendix A.

**[45CSR13, Permit No. R13-2068 (Condition 5.2.1.)]**

#### **4.3. Testing Requirements**

- 4.3.1. Reserved.

#### **4.4. Recordkeeping Requirements**

- 4.4.1. A record of each visible emission check shall be maintained on site for five (5) years from the record creation date. Such record shall include, but not be limited to, the date, time, name of emission unit, the applicable visible emissions requirement, the results of the check, what action(s), if any, was/were taken, and the name of the observer.

**[45CSR13, Permit No. R13-2068 (Condition 5.4.2.)]**

#### **4.5. Reporting Requirements**

- 4.5.1. See Section 3.5.

#### **4.6. Compliance Plan**

- 4.6.1. None



**5.0 Source-Specific Requirements - Fluid Bed Granulators [Controlled by Cartridge Collectors] (533, 534, 535, 536, 537, 538, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, and 582)**

**5.1. Limitations and Standards**

- 5.1.1. No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any process source operation, which is greater than twenty (20) percent opacity.  
**[45CSR§7-3.1 and 45CSR13, Permit No. R13-2068 (Condition 6.1.1.)]**
- 5.1.2. Maximum PM emissions from each Fluid Bed to the atmosphere shall not exceed 0.1 pounds per hour and 0.1 tons per year.  
**[45CSR § 7-4.1. and 45CSR13, Permit No. R13-2068 (Condition 6.1.3.)]** *Compliance with this streamlined limit will assure compliance with 45CSR § 7-4.1. and Permit No. R13-2068 (Condition 6.1.2.)*

- 5.1.3. ~~Particulate matter emissions from the fluid beds shall be vented to and controlled by cartridge collectors prior to release to the atmosphere. The cartridge collectors shall be designed to achieve a collection efficiency of 95% for particulate matter emissions.~~

The fluid beds shall operate according to the following requirements:

- a. The aggregate dry material loading of the fluid bed (excluding times of tablet coating in a fluid bed) shall not exceed the following limits:
- (1) Fluid Beds 534, 536, 538, 572, 574, 575, 577: 154 kg/load
  - (2) Fluid Beds 533, 535, 537, 571, 573, 576, 578, 579, 580, 581, 582: 550 kg/load
- b. The annual aggregate dry material loading of all fluid beds shall not exceed 99,000,000 pounds on a rolling yearly total basis.
- c. Cartridge collectors shall be used at all times on each fluid bed to control particulate matter emissions. Each collector shall, at a minimum, achieve a collection efficiency of 95%.
- d. The spray rate used in each fluid bed shall not exceed 4 kilograms-VOC/minute.
- e. No HAP-containing solvents shall be processed in any fluid bed.

**[45CSR13, Permit No. R13-2068 (Condition ~~6.1.4,~~ 6.1.6.)]**

- 5.1.4. Maximum hourly VOC emissions to the atmosphere from each Fluid Bed shall not exceed ~~187.5~~ 529.2 pounds per hour.  
**[45CSR13, Permit No. R13-2068 (Condition ~~6.1.5,~~ 6.1.4.)]**
- 5.1.5. Maximum total combined annual VOC emissions to the atmosphere from the Fluid Beds shall not exceed ~~99.0~~ 110.0 tons per year.  
**[45CSR13, Permit No. R13-2068 (Condition ~~6.1.6,~~ 6.1.5.)]**
- 5.1.6. ~~Maximum non-HAP alcohol emissions to the atmosphere from each Fluid Bed shall not exceed 187.5 pounds per hour. The maximum non-HAP alcohol usage for all fluid beds shall not exceed 99.0 tons per year.~~  
**[45CSR13, Permit No. R13-2068 (Condition 6.1.7.)]**

## 5.2. Monitoring Requirements

- 5.2.1. ~~The permittee shall operate and maintain the cartridge collectors and the permittee shall conduct a weekly visual inspection of the filters and connections at each emission point specified, in order to ensure proper operation of the cartridge collectors.~~

The permittee shall operate and maintain the cartridge collectors and shall conduct a weekly visual inspection of the cartridge, cartridge connections, and dust hoppers of each cartridge collector, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.

**[45CSR13, Permit No. R13-2068 (Condition 6.2.2.)]**

- 5.2.2. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR 60, Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

**[45CSR13, Permit No. R13-2068 (Conditions 6.2.1.)]**

- 5.2.3. For the purposes of demonstrating compliance with maximum dry material loading set forth in 5.1.3.a., the permittee shall monitor and record the total dry material per load for each fluid bed. This requirement may be waived if the permittee is able to demonstrate that the maximum reasonable design capacity of each fluid bed is equal or less than the maximum load given under 5.1.3.a. or if the permittee is able to demonstrate that the maximum loading based on product formulations is equal or less than the maximum load given under 5.1.3.a.  
**[45CSR13, Permit No. R13-2068 (Conditions 6.2.3.)]**

- 5.2.4. For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 5.1.3.b., the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material into the fluid beds.  
**[45CSR13, Permit No. R13-2068 (Conditions 6.2.4.)]**

- 5.2.5. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 5.1.5, the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in the fluid beds.  
**[45CSR13, Permit No. R13-2068 (Conditions 6.2.5.)]**

### 5.3. Testing Requirements

- 5.3.1. See Section 3.3.1.

### 5.4. Recordkeeping Requirements

- 5.4.1. ~~Records generated as a result of the monitoring requirements in subsection 5.2.1. shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each collector inspection, the inspection results, and the corrective action(s) taken, if any.~~

The permittee shall maintain a record of all solvents used in the fluid beds and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs.

[45CSR13, Permit No. R13-2068 (Condition ~~6.2.2.~~ & 6.4.2.)]

- 5.4.2. ~~To demonstrate compliance with the emission limits and Non-HAP alcohol usage limits set forth in 5.1.4., 5.1.5., 5.1.6., the permittee shall keep monthly records of Non-HAP alcohol used, the number of batches in which Non-HAP alcohol was used, the number of hours for each batch, and provide calculations necessary to show compliance or noncompliance.~~

Records of weekly inspections conducted on the cartridge collector shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.

[45CSR13, Permit No. R13-2068 (Condition 6.4.1.)]

### 5.5. Reporting Requirements

- 5.5.1. See Section 3.5.

### 5.6. Compliance Plan

- 5.6.1. None.

**6.0. Source-Specific Requirements • Rotoclones (280, 281, 282, 283, 287, 288, 291, 294, 295, 296, 297, 298, 299, 300, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321)**

**6.1. Limitations and Standards**

6.1.1. No person shall cause, suffer, allow or permit emission of smoke and /or particulate matter into the open air from any process source operation, which is greater than twenty (20) percent opacity.  
**[45CSR§7-3.1. and 45CSR13, Permit No. R13-2068 (Condition 7.1.1.)]** *(All units listed above)*

6.1.2. No person shall cause, suffer, allow or permit particulate matter to be vented into the open air from any type source operation or duplicate source operation, or from all air pollution control equipment installed on any type source operation or duplicate source operation in excess of the quantity specified under the appropriate source operation type in Table 45-7A found at the end of 45CSR7. Based on the process weight rates for the Pharmaceutical manufacturing equipment serviced by Rotoclones (280, 281, 282, 283), 1000 pounds per hour each, the corresponding allowable particulate matter emission rate is 1.2 pounds per hour each.  
**[45CSR§7-4.1. and Permit No. R13-2068 (Condition 7.1.2.)]**

6.1.3. Maximum particulate matter emissions to the atmosphere shall not exceed the following:

Source	Maximum PM Hourly Emissions (lb/hr)
Rotoclone (287)	0.4
Rotoclone (288)	0.4
Rotoclone (291)	0.4
Rotoclone (294)	0.4
Rotoclone (295)	0.4

**[45CSR§7-4.1. and Permit No. R13-2068 (Condition 7.1.3.)]** *Compliance with this streamlined limit will assure compliance with 45CSR§7-4.1.and Permit Number R13-2068( Condition 7.1.2.)*

6.1.4. Emissions from the North Expansion Area pharmaceutical processing equipment rooms shall be vented to and controlled by a Rotoclone Wet Scrubber/Dust Collector (Control Device 296 through 300, and 305 through 321) prior to release to the atmosphere.  
**[45CSR13, Permit No. R13-2068 (Condition 7.1.5.)]**

6.1.5. Maximum particulate matter (PM) emissions to the atmosphere from the North Expansion Area pharmaceutical processing equipment rooms through each Control Device 296 through 300, and 305 through 321 shall not exceed a maximum hourly emission rate of 0.71 pounds per hour (lb/hr) and 1.76 tons per year (tpy).  
**[45CSR§7-4.1. and 45CSR13, Permit No. R13-2068 (Condition 7.1.6.)]** *(296, 297, 298, 299, 300, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321) Compliance with this streamlined limit will assure compliance with 45CSR§7-4.1.and Permit R13-2068 (Condition 7.1.2.).*

6.1.6. The Rotoclone control devices shall be designed to achieve a collection efficiency of 98% for particulate matter emissions.  
**[45CSR13, Permit No. R13-2068 (Condition 7.1.4.)]**

6.1.7. The permittee shall maintain and operate low water supply pressure sensors with control panel alarms for each Rotoclone to ensure adequate water supply and flow rate to the Rotoclones at each emission point specified, in order to ensure proper operation of the Rotoclone.  
**[45CSR13, Permit No. R13-2068 (Condition 7.1.7.)]**

## 6.2. Monitoring Requirements

- 6.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR 60, Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

[45CSR13, Permit No. R13-2068 (Conditions 7.2.1.)]

## 6.3. Testing Requirements

- 6.3.1. See Subsection 3.3.1.

## 6.4. Recordkeeping Requirements

- 6.4.1. A record of each visible emission check shall be maintained on site for five (5) years from the record creation date. Such record shall include the date, time, name of emission unit, the applicable visible emissions requirement, the results of the check, what action(s), if any, was/were taken, and the name of the observer.

[45CSR13, Permit No. R13-2068 (Condition 7.4.1.)]

- 6.4.2. Records of Rotoclone low water supply pressure sensor alarm shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each Rotoclone low water supply pressure sensor alarm, ~~the cause of the alarm, and corrective actions taken, if any.~~

[45CSR13, Permit No. R13-2068 (Condition 7.4.2.)]

## 6.5. Reporting Requirements

- 6.5.1. See Section 3.5.

## 6.6. Compliance Plan

- 6.6.1. None

## 7.0 Source-Specific Requirements • Coating Pans (210, 215, 220, 230, 240, [241](#), [242](#), [243](#), [244](#))

### 7.1. Limitations and Standards

7.1.1 No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any process source operation, which is greater than twenty (20) percent opacity.  
**[45CSR§7-3.1. and 45CSR13, Permit No. R13-2068 Condition 8.1.1.)]**

7.1.2. No person shall cause, suffer, allow or permit particulate matter to be vented into the open air from any type source operation or duplicate source operation, or from all air pollution control equipment installed on any type source operation or duplicate source operation in excess of the quantity specified under the appropriate source operation type in Table 45-7A found at the end of 45CSR7. Based on the process weight rates for the Coating Pans (excluding Emission Unit ID No. 215, [241](#), [242](#), [243](#), and [244](#)), 333 pounds per hour each, the corresponding allowable particulate matter emission rate is 0.4 pounds per hour each. [Based on the process weight rates for Coating Pans 243, 750 pounds per hour, the corresponding allowable particulate matter emission rate is 0.9 pounds per hour.](#)  
**[45CSR§7-4.1] (210, 220, 230, 240, [243](#))**

7.1.3. Particulate matter emissions from the Coating Pan, venting through a cartridge collector (215, [241](#), [242](#), [244](#)) at Emission Point ID No. 215, [241](#), [242](#), and [244](#), shall not exceed the following:

Emission Unit	PM Emission Limit	
	Pounds per Hour	Tons per Year
215	<del>0.28</del> <a href="#">0.56</a>	<del>4.20</del> <a href="#">6.24</a>
<a href="#">241</a>	<a href="#">0.84</a>	
<a href="#">242</a>	<a href="#">0.28</a>	
<a href="#">244</a>	<a href="#">0.84</a>	

**[45CSR§7-4.1 and 45CSR13, Permit No. R13-2068 (Condition 8.1.3)]** (215, [241](#), [242](#), [244](#)) *Compliance with this streamlined limit will assure compliance with 45CSR§7-4.1. and R13-2068 (Condition 8.1.2.).*

7.1.4. [Maximum hourly volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed 396.9 lb/hr for each coating pan unit.](#)  
**[45CSR13, Permit No. R13-2068 (Condition 8.1.4.)]**

7.1.5. [Maximum total combined annual volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed 5.0 tons/year.](#)  
**[45CSR13, Permit No. R13-2068 (Condition 8.1.5.)]**

7.1.6. [The coating pans shall operate according to the following requirements:](#)

a. [The aggregate dry material loading of each coating pan shall not exceed the following values:](#)

- (1) [Coating Pan 215: 750 pound/load;](#)
- (2) [Coating Pan 241: 750 pound/load;](#)
- (3) [Coating Pan 242: 245 pound/load;](#)
- (4) [Coating Pan 244: 750 pound/load.](#)

- b. The annual aggregate dry material loading of all coating pans shall not exceed 11,000,000 pounds on a rolling yearly total basis.
- c. Cartridge collectors shall be used at all times on each coating pan to control particulate matter emissions. Each collector shall, at a minimum, achieve a collection efficiency of 95%.
- d. The solvent spray rate processed in coating pans 241, 242, and 244 shall not exceed 3,000 grams-VOC/minute in each coating pan.
- e. No VOC-containing solvents shall be processed in coating pan 215.
- f. No HAP-containing solvents shall be processed in any coating pan.

[45CSR13, Permit No. R13-2068 (Condition 8.1.6.)]

## 7.2. Monitoring Requirements

- 7.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR 60, Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

[45CSR13, Permit No. R13-2068 (Condition 8.2.1.)] (215, 241, 242, 244)

- 7.2.2. The permittee shall operate and maintain the cartridge collectors and shall conduct a weekly visual inspection of the cartridge, cartridge connections, and dust hoppers of each cartridge collector, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.

[45CSR13, Permit No. R13-2068 (Condition 8.2.2.)]

- 7.2.3. For the purposes of demonstrating compliance with maximum dry material loading set forth in 7.1.6.a., the permittee shall monitor and record the total dry material per load for each coating pan. This requirement may be waived if the permittee is able to demonstrate that the maximum reasonable design capacity of each coating pan is equal or less than the maximum load given under 7.1.6.a. or if the permittee is able to demonstrate that the maximum loading based on product formulations is equal or less than the maximum load given under 7.1.6.a.

[45CSR13, Permit No. R13-2068 (Condition 8.2.3.)]

- 7.2.4. For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 7.1.6.b., the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material loaded into the coating pans.

[45CSR13, Permit No. R13-2068 (Condition 8.2.4.)]

- 7.2.5. [For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 7.1.5, the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in coating pans 241, 242, and 244.](#)  
[\[45CSR13, Permit No. R13-2068 \(Condition 8.2.5.\)\]](#)

### **7.3. Testing Requirements**

- 7.3.1. See 3.3.1.

### **7.4. Recordkeeping Requirements**

- 7.4.1. [Records of weekly inspections conducted on the cartridge collector shall be maintained on site for five \(5\) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.](#)  
[\[45CSR13, Permit No. R13-2068 \(Condition 8.4.1.\)\]](#)
- 7.4.2. [The permittee shall maintain a record of all solvents used in the coating pans and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs.](#)  
[\[45CSR13, Permit No. R13-2068 \(Condition 8.4.2.\)\]](#)

### **7.5. Reporting Requirements**

- 7.5.1. See Section 3.5.

### **7.6. Compliance Plan**

- 7.6.1. None.



## **8.0 Source-Specific Requirements • Regenerative Thermal Oxidizer (RTO) and Catalytic Oxidizer (CO)**

### **8.1. Limitations and Standards**

- 8.1.1. The permittee shall not cause, suffer, allow or permit particulate matter to be discharged from the RTO or CO into the open air in excess of the quantity determined by use of the following formula:

$$\text{Emissions (lb/hr)} = F \times \text{Incinerator Capacity (tons/hr)}$$

Where, the factor, F, is as indicated below:

<u>Incinerator Capacity</u>	<u>Factor F</u>
<u>A. Less than 15,000 lbs/hr</u>	<u>5.43</u>
<u>B. 15,000 lbs/hr or greater</u>	<u>2.72</u>

The expected maximum loading of the RTO(s) is 1.54 tons/hour (3,070 lbs/hr). Using this value in the above equation produces a PM emission limit of 8.36 lb/hr for the RTO(s). However, the RTO(s) are limited to emit a maximum 2.66 lb/hr of particulate matter in Condition 8.1.3.

The expected maximum loading of the CO is 0.23 tons/hour (450 lbs/hr). Using this value in the above equation produces a PM emission limit of 1.22 lb/hr for the CO. However, the CO is limited to emit a maximum 0.35 lb/hr of particulate matter in Condition 8.1.3.

**[45CSR§6-4.1 and 45CSR13, Permit No. R13-2068 (Condition 9.1.1.)]**

- 8.1.2. The permittee shall not cause or allow emission of smoke into the atmosphere from the RTO or CO which is twenty percent (20%) opacity or greater. The provisions of 45CSR§6-4.3 shall not apply to smoke which is less than forty percent (40%) opacity, for a period or periods aggregating no more than eight (8) minutes per start-up, or six (6) minutes in any sixty (60)-minute period for stoking operations.  
**[45CSR§6-4.3 and 4.4 and 45CSR13, Permit No. R13-2068 (Condition 9.1.2.)]**

- 8.1.3. Maximum emissions to the atmosphere RTO and CO shall not exceed the values given in the following tables:

**RTO Emission Limits**

<u>Pollutant</u>	<u>Maximum Hourly Emissions (lb/hr)</u>	<u>Maximum Annual Emissions (tpy)</u>
<u>Carbon Monoxide</u>	<u>28.57</u>	<u>9.61</u>
<u>Nitrogen Oxides</u>	<u>48.89</u>	<u>13.91</u>
<u>Particulate Matter<sup>(1)</sup></u>	<u>2.66</u>	<u>0.89</u>
<u>Sulfur Dioxide</u>	<u>0.08</u>	<u>0.05</u>
<u>Volatile Organic Compounds</u>	<u>61.48</u>	<u>6.53</u>

(1) All particulate matter emissions are assumed to be PM<sub>10</sub> or less.

CO Emission Limits

<u>Pollutant</u>	<u>Maximum Hourly Emissions (lb/hr)</u>	<u>Maximum Annual Emissions (tpy)</u>
<u>Carbon Monoxide</u>	<u>3.78</u>	<u>0.87</u>
<u>Nitrogen Oxides</u>	<u>6.50</u>	<u>1.26</u>
<u>Particulate Matter<sup>(1)</sup></u>	<u>0.35</u>	<u>0.08</u>
<u>Sulfur Dioxide</u>	<u>0.02</u>	<u>0.01</u>
<u>Volatile Organic Compounds</u>	<u>9.01</u>	<u>1.03</u>

(1) All particulate matter emissions are assumed to be PM<sub>10</sub> or less

[45CSR13, Permit No. R13-2068 (Condition 9.1.3.)]

8.1.4. Regenerative Thermal Oxidation shall be operated according to the following requirements:

- a. The permittee is authorized to operate one or two regenerative thermal oxidizers.
- b. The aggregate MDHI of the natural gas burner(s) shall not exceed 13.75 mmBtu/hr.
- c. The aggregate annual amount of natural gas consumed by the RTO(s) shall not exceed 120.45 million cubic feet per rolling twelve month total.
- d. The aggregate maximum amount of solvent combusted by the RTO(s) shall not exceed 3,070 lb/hour or 26,893,200 pounds per rolling twelve month period.

[45CSR13, Permit No. R13-2068 (Condition 9.1.4.)]

8.1.5. The Catalytic Oxidizer shall be operated according to the following requirements:

- a. The aggregate MDHI of the natural gas burner(s) shall not exceed 1.25 mmBtu/hr.
- b. The aggregate annual amount of natural gas consumed by the CO shall not exceed 10.95 million cubic feet per rolling twelve month total.
- c. The aggregate maximum amount of solvent combusted by the CO shall not exceed 450 lb/hour or 3,942,000 pounds per rolling twelve month period.

[45CSR13, Permit No. R13-2068 (Condition 9.1.5.)]

**8.2. Monitoring Requirements**

8.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR , Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

[45CSR13, Permit No. R13-2068 (Condition 9.2.1.)]

8.2.2. For the purposes of demonstrating compliance with maximum annual natural gas combustion rates set forth in 8.1.4(c) and 8.1.5(c), the permittee shall monitor and record the rolling twelve month total of natural gas combusted by the RTO(s) and CO.

[45CSR13, Permit No. R13-2068 (Condition 9.2.2.)]

8.2.3. For the purposes of demonstrating compliance with maximum annual solvent combustion rates set forth in 8.1.4(d) and 8.1.5(d), the permittee shall monitor and record the rolling twelve month total of solvent combusted by the RTO(s) and CO.

[45CSR13, Permit No. R13-2068 (Condition 9.2.3.)]

### 8.3. Testing Requirements

8.3.1. Within 60 days after achieving the maximum solvent combustion rate at which the RTO(s) are permitted to operated at, but not later than 180 days after initial startup, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the RTO(s) to determine compliance with the CO and NO<sub>x</sub> emission limits listed in 8.1.3. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.

[45CSR13, Permit No. R13-2068 (Condition 9.3.1.)]

### 8.4. Recordkeeping Requirements

8.4.1. See Section 3.4

### 8.5. Reporting Requirements

8.5.1. See Section 3.5

### 8.6 Compliance Plan

8.6.1. None.